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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,535	10/12/2005	Josef Prassler	MS027US	8828
81777 MorphoSys AG Lena-Christ-Str. 48 Martinsried/Planegg, 82152 GERMANY	7590 09/03/2010			
EXAMINER				
VOGEL, NANCY TREPTOW				
ART UNIT		PAPER NUMBER		
1636				
NOTIFICATION DATE		DELIVERY MODE		
09/03/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmailbox@morphosys.com  
paul.wiegel@morphosys.com

**Office Action Summary****Application No.**

10/522,535

**Applicant(s)**

PRASSLER ET AL.

**Examiner**

NANCY VOGEL

**Art Unit**

1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 9-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/11/10 has been entered.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claims 1, 3-5, 9-19 are pending in the case.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "said nucleic acid encoding the Ig-presenting polypeptide" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claims 3-5, 9-19 recites the limitation "the tricistronic vector construct according to claim 1" in line 1 of each claim (directly or indirectly). There is insufficient antecedent basis for this limitation in the claim on which the claims depend, i.e. claim 1. Claim 1 recites a library of vector constructs, not a single vector.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohning et al. (US 2002/0034733) in view of Kozak (Microbiological Reviews, 47 (1) 1-45, 1983)(newly cited).

Lohning disclose phagemid vectors [0010] comprising a prokaryotic promoter (Fig. 16a) , a first nucleic acid sequence encoding an immunoglobulin-presenting polypeptide, which may be the phage coat protein gIII [0015] or fragment thereof [0017], a second nucleic acid sequence encoding a first Ig polypeptide, and a third nucleic acid sequence encoding a second Ig polypeptide [0050]. See Figs. 6a, 7a, 16a. A first and second associating agent are fused to or comprised within said Ig-

presenting polypeptide and the first Ig polypeptide [0008, 0009, 0010]. The reference discloses that the first and second Ig polypeptides self-associate to form a Fab or other functional Ig fragment, via non-covalent interactions [0156]. The reference discloses that the first and second associating agents associate with each other via disulfide bond, and is a cysteine residue [0054]. The reference discloses prokaryotic secretory signal sequences in the same reading frame as each of the nucleic acid sequences [0156-0157]. The associating agents would become disassociated in solution upon the addition of a reducing agent [0070]. The vector comprises a ribosome binding site positioned 5' to the nucleic acid sequence encoding each of the first, second and third polypeptide, since it is shown in the reference that proteins are produced using the disclosed expression vectors, and therefore at least one ribosome binding site is present in the normal, 5' region of the start site of the polypeptide encoding region. The reference exemplifies the use of two vectors, with one encoding the Ig presenting polypeptide pIII, and a bicistronic vector encoding the heavy and light chain, with each comprising a signal sequence upstream of the coding region, wherein the resultant Fab is linked to the pIII protein via disulfide bond (Example 2.2). The difference between the reference and the instant claims is that a single tricistronic vector carrying all components is not disclosed.

However, Kozak discloses that mRNA structure in prokaryotes, is polycistronic, with transcription of multiple genes to form a polycistronic primary transcript that functions as mRNA. Kozak discloses that this is the primary type of regulatory device used by prokaryotes. (page 12-15). Phage display is disclosed by Lohning and is well

known in the art, to utilize bacterial cells as host cells. Therefore, it would have been to one of skill in the art who wished to simultaneously express three structural proteins including two proteins of an immunoglobulin, and one protein which is a phage coat protein, as disclosed by Lohning et al., that a polycistronic (tricistronic in particular) arrangement of the three coding genes under the control of a single promoter, would be appropriate for such expression in a prokaryotic cell. One would have been motivated to do so by the desire to obtain simultaneous expression of three genes, under a single control. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
8/30/10